



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

94849d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA HAND DELIVERY**

Our Reference No. 1000123954

June 23, 2004

Ronald M. Foster, Manager  
Randall C. Boyce, Manager  
Trevor O. Foster, Manager  
George P. Foster, Manager  
Fresno Farming LLC  
P.O. Box 457  
1000 Davis Street  
Livingston, California

**WARNING LETTER**

Dear Msrs. Foster, Boyce, Foster, and Foster:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your medicated animal feed mill operation, Fresno Farming LLC, located in Traver, California from April 14, 2004 through May 6, 2004, and found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Section 589.2000 (21 C.F.R. § 589.2000)—Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Because you failed to follow this rule, products you manufactured and distributed are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Our inspection found the following violations of 21 C.F.R. § 589.2000:

1. Failure to provide for measures to avoid commingling or cross-contamination of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants to comply with 21 C.F.R. § 589.2000(e)(1)(iii).

- Your firm uses a vacuum system to clean up spilled product in the tunnel area. This tunnel area houses the two receiving conveyor systems and the elevators for

the two conveyor systems. When product, including ruminant meat and bone meal, is spilled onto the floor of this area, the spilled product is vacuumed up by the vacuum system and, via a discharge hose, was placed into a conveyor system that your firm had designated as free of ruminant meat and bone meal. Your firm admitted that it was unaware of the vacuum system discharging into the conveyor systems designated as free of ruminant meat and bone meal and that this had been in place since April 2003. Your firm remedied this problem during FDA's April/May 2004 inspection by removing the discharge hose connection to the conveyor system that your firm had designated as free of ruminant meat and bone meal.

- Your firm uses a dust collection system that pulls dust from systems that receive both ruminant meat and bone meal and feed ingredients intended for ruminants. This dust system then discharged collected product back into the two conveyor systems via a cross connection, thereby making it likely that ruminant meat and bone meal became commingled with ruminant feed ingredients. Your firm admitted that it was unaware of the cross connection and that it had been in place since April 2003. Your firm removed the cross connection during FDA's April/May 2004 inspection.

2. Failure to maintain written procedures specifying the clean-out procedure or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment, to comply with 21 C.F.R. § 589.2000(e)(1)(iv). This observation was also noted during FDA's July/August 2003 inspection of your firm.

- There are no written procedures for separating products that contain prohibited material from ingredients used in ruminant feeds from the time of receipt until the time of shipment.
- The written procedure for cleaning out or flushing equipment after mixing feeds containing prohibited material was not adequate to prevent contamination of ruminant feed with prohibited material.

3. Failure to maintain records sufficient to track materials that contain protein derived from mammalian tissues throughout their receipt, processing, and distribution to comply with 21 C.F.R. § 589.2000(e)(1)(i). This observation was also noted during FDA's July/August 2003 inspection of your firm.

- Specifically, your firm has failed to develop and implement complete written procedures to separate ruminant meat and bone meal from feed ingredients intended for ruminants from the time of receipt until the time of distribution. The written procedures that do exist fail to address the use of equipment common to ruminant meat and bone meal and ruminant feed ingredients.

The above is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for use as animal feed, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective actions cannot be completed in fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the U.S. Food and Drug Administration, Attention: Ms. Harumi Kishida, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

*C D Moss, Acting DD*

*for*

Barbara J. Cassens  
District Director  
San Francisco District

cc: VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED  
C. Michael Blasco, Feed Mill Manager  
Fresno Farming LLC  
P.O. Box 430  
Traver, California 93673